K052430

OCT 4 - 2005

**Appendix 2: 510(k) Summary**

## A. Sponsor

Digirad Corporation
13950 Stowe Drive
Poway, California 92064
Contact Person: Joel Tuckey
Tel: (858) 726-1527
Fax: (858) 726-1700

## B. Date Prepared: September 2, 2005

## C. Device Name

Trade Name: Cardius-1, Cardius-2, Cardius-3, 2020tc SPECT Imaging System
Classification Name: System, Emission Tomography

## D. Description of Changes

The changes to the Digirad 2020tc and Cardius SPECT imaging cameras involve addition of an Image Stabilization System. The proposed Image Stabilization System is used to correct image studies for patient motion in SPECT data acquired with Digirad Nuclear medicine gamma camera systems. The Image Stabilization System consists of two parts: a Hardware component that mounts to the SPECT Imaging System, and a software module that collects data from the hardware and corrects the image data for motion. The resulting motion corrected patient study data is referred to as the Image Stabilized Patient Study. The Image Stabilization system may operate only with the above described Digirad Camera models and is compatible with proprietary Digirad Acquisition Software under the Windows Operating system and standard PC architecture.

The proposed Image Stabilization System performs substantially the same function as the currently cleared Cedar's Sinai Motion Correction Program (MoCo), cleared for use on Digirad SPECT Imaging Systems under Digirad 510(k) #K023110.

The proposed Image Stabilization System automatically produces an Image Stabilized Patient Study, corrected for patient motion, which is available in the existing database. The original image study is produced in an identical manner as in the previously cleared devices. Both studies are stored in the same patient record in the database. Additional minor changes were made to the User Interface screen.

The Image Stabilized Patient Studies produced by the proposed device are identical in file structure to the original, unmodified data set; therefore SeeQuanta 1.2 and the Image Stabilization System are fully compatible with the same database, reconstruction software, and processing software that is used with the "cleared" devices. Hence, there are no changes to these software modules.

This proposed optional software addition will be available to Digirad customers both integrated with the Digirad 2020tc SPECT Imaging System, and Cardius-1, Cardius-2, and

Cardius-3 SPECT Imaging Systems, and separately as a retrofit device for existing Digirad Product Customers.

## E. Intended Use

The intended uses of the Cardius and 2020tc cameras have not changed, and are summarized in the "Indications for Use" form included with this submission.

## F. Cleared/Predicate Device

The proposed change is a modification to the following Digirad cleared devices:

(1) 2020tc SPECT Imaging System and the SPECTour Chair (SPECT Imaging System), cleared on November 9, 1998 under 510(k) #K982855; and

(2) Cardius-1 and Cardius-2 SPECT Imaging System cleared on February 5, 2003 under 510(k) #K030085.

(3) Cardius-1, Cardius-2, Cardius-3, and 2020tc SPECT Imaging Systems cleared on July 13, 2005 under 510(k) #K051549

The Image Stabilization System Accessory when integrated with the cleared 2020tc and Cardius Model Digirad SPECT Imaging Systems has the same function as the following predicate devices: the Motion Correction function module of Mirage software device (Segami Corporation, #K972886) and Digirad Cedars-Sinai Motion Correction (MoCo) Software Program device (#K023110), which is currently used on the Digirad 2020tc and Cardius models SPECT imaging Systems to carry out patient motion correction to the post-processed data.

Additionally, the proposed Image Stabilization System also performs the same functions as the MoCo Motion Correction Software in the following predicate devices: Cedars-Sinai BPGS and MoCo cleared under K010509 for GE/SMV America, and QPS/BPGS/MoCo Processing Applications cleared under K003264 for ELGEMS Ltd.

## G. Conclusions Drawn from Testing

Testing was performed to analyze the content of corrected phantom studies using the Image Stabilization Accessory integrated with the Digirad Cardius-1 camera. Also extensive Verification testing was completed on all cleared Digirad SPECT Imaging Systems integrated with the Image Stabilization Device to demonstrate that the design outputs met the design inputs of the proposed Image Stabilization Accessory Device. Testing included comprehensive phantom image verification and validation studies with modified acquisition software. All software test results met pre-defined acceptance criteria. The quality of the phantom images corrected with the Image Stabilization System with the modified acquisition software was similar to the quality of the images post-processed corrected using the MoCo Motion Correction program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2005

Mr. Joel Tuckey
VP Quality
Digirad Corporation
13950 Stowe Drive
POWAY CA 92064-8803

Re: K052430
Trade/Device Name: Cardius-1, Cardius-2, Cardius-3, 2020c SPECT Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: September 2, 2005
Received: September 6, 2005

Dear Mr. Tuckey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use
510(k) Number (if known): ~~n/a~~ K052430
Device Name: Cardius-1, Cardius-2, Cardius-3, 2020tc SPECT Imaging System

Indications for Use:

Cardius-1, Cardius-2, Cardius-3:

The Cardius product models are intended for use in the generation of cardiac studies, including planar and Single Photon Emission Computed Tomography (SPECT) studies, in nuclear medicine applications.

2020tc SPECT Imaging System:

The Digirad 2020tc SPECT Imaging system is intended for use in the generation of both planar and Single Photon Emission Computed Tomography (SPECT) clinical images in nuclear medicine applications. The Digirad SPECT Rotating Chair is used in conjunction with the Digirad 2020tc Imager™ to obtain SPECT images in patients who are seated in an upright position.

Specifically, the 2020tc Imager™ is intended to image the distribution of radionuclides in the body by means of a photon radiation detector. In so doing, the system produces images depicting the anatomical distribution of radioisotopes within the human body for interpretation by authorized medical personnel.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052430